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(54) Method of making bifurcated stent with improved side branch aperture

Herstellungsverfahren für abzweigenden Stent mit verbesserter Nebenöffnung

Méthode pour la manufacture d'un stent avec bifurcation à branche latérale améliorée

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Description

Field of the Invention

[0001] The present invention relates to a method of making a stent.

Background of the Invention

[0002] Stents are well known in the art. They are typically formed of a cylindrical metal mesh which can expand when pressure is internally applied. Alternatively, they can be formed of wire wrapped into a cylindrical shape or sheets of material formed into a cylindrical shape.

[0003] Stents are devices which are usually implanted within bodily conduits including the vascular system to reinforce collapsing, partially occluded, weakened, or abnormally dilated sections of the blood vessel. Stents also have been successfully implanted in other areas, e.g., the urinary tract or the bile duct to reinforce such bodily conduits.

[0004] U.S. Patent No. 4,994,071 (MacGregor) discloses an expandable, bifurcating stent having a main cylindrical lattice formed from interconnected flexible wire. Two additional cylindrical lattices, having smaller diameters than the main lattice, are similarly constructed. The main lattice includes a flexible wire interconnecting the main lattice to one of the additional lattices. A second flexible wire interconnects the main lattice to the other additional lattice. The flexible wires form backbones that extend axially along the length of the main lattice and along each of the additional lattices. One disadvantage of this bifurcating stent is the complex nature of the interconnection of the flexible wires forming the backbones with the loop structure of each lattice.

[0005] EP 0 956 832 A1 discloses a method of making a stent as defined in the precharacterizing portion of claim 1, whereby the stent is made out of a six-sided "L"-shaped sheet.

SUMMARY OF THE INVENTION

[0006] The problem of the present invention is to simplify the method of making a stent as known from EP 0 956 832 A1.

[0007] This problem is solved according to the invention by a method as defined in claim 1. An advantageous embodiment of the inventive method is claimed in dependent claim 2.

[0008] The "T"-shaped sheet of the present invention makes the rolling step of the sheet and the connecting step of the corresponding sides simpler, because an additional rotation of the stent is necessary according to the prior art as known from EP 0 956 832 A1 to connect the second pair of opposed sides after the first pair of opposed sides has been connected.

Brief description of the drawings:

[0009]

FIG. 1 shows an embodiment of a sheet used to form a stent in accordance with the invention;
FIG. 1A shows a stent manufactured utilizing the sheet of FIG. 1;
FIG. 2 shows a sheet used to form a stent in accordance with the invention; and
FIG. 3 shows the first expandable tubular member of FIG. 1A with a second expandable tubular member disposed within the side branch aperture.

Detailed Description

[0010] FIG. 1, shows an embodiment of a sheet 514 used to make a stent in accordance with the present invention. FIG. 1 shows a sheet 514 having a longitudinal axis 515 and a first portion 516 and a second portion 517. The first portion 516 has a proximal end 518 and a distal end 519 and a first lateral side 520 and a second lateral side 521. The lateral sides 520 and 521 of the first portion 516 are substantially parallel to the longitudinal axis 515 and are disposed apart from each other a first distance d1 522. The second portion 517 has a proximal end 523 and a distal end 524 and a first lateral side 525 and a second lateral side 526. The lateral sides 525 and 526 of the second portion 517 are substantially parallel to the longitudinal axis 515 and are disposed apart from each other a second distance d2 527 that is less than the first distance d1 522. The proximal end 523 of the second portion 517 communicates with the distal end 519 of the first portion 516. Making a stent utilizing the sheet of FIG. 1 comprises the steps of connecting the first lateral side 520 of the first portion 516 to the second lateral side 521 of the first portion 516 and connecting the first lateral side 525 of the second portion 517 to the second lateral side 526 of the second portion 517 to form a first tubular member 539 having a longitudinal bore 528 therethrough as shown in FIG. 1A. A portion of the distal end 519 of the first portion 516 and a portion of the proximal end 523 of the second portion 517 define a side branch aperture 529.

[0011] The sheet of FIG. 1 may also be described as a sheet 530 having a first side 531, a second side 532 , a third side 533, a fourth side 534, a fifth side 535, a sixth side 536, a seventh side 537, and an eighth side 538 as shown in FIG. 2. Making a stent 539 utilizing the sheet shown in FIG. 2 comprises the steps of connecting the second side 532 to the eighth side 538 and connecting the fourth side 534 to the sixth side 536 to form a stent 539 having a longitudinal bore 528 therethrough and wherein the third side 533 and the seventh side 537 define a branch aperture 529 disposed between the first side 531 and the fifth side 535 as shown in FIG. 1A If it is desired to make a bifurcated stent 511, a second tubular member 512 having a longitudinal bore 513 is dis-

posed and secured within the branch aperture 529 of the first tubular member 539 so that the longitudinal bore 513 of the second tubular member 512 is in fluid communication with the longitudinal bore 528 of the first tubular member 539 as shown in Fig. 3.

[0012] An especially preferred method of making a bifurcated stent comprises the steps of preparing a first expandable tubular member having a proximal end and a distal end and a longitudinal bore therethrough. The first tubular member is provided with a branch aperture disposed between the proximal end and the distal end. The branch aperture communicates with the longitudinal bore of the first expandable tubular member and the aperture is sized and adapted to receive and secure a second expandable tubular member. The first expandable tubular member is delivered to a bifurcated vessel having a first lumen and a second lumen so that the first expandable tubular member is disposed within the first lumen and the branch aperture communicates with the second lumen. The branch aperture is widened in an amount sufficient to further align the branch aperture with the second lumen. As specific applications dictate, the portion of the first expandable tubular member defining the branch aperture may be adapted to form a branch securing lip when the branch aperture is expanded a sufficient amount. The first expandable tubular member is then expanded an amount sufficient to secure the first expandable tubular member in the first lumen. A second expandable tubular member is prepared having a proximal end and a distal end having longitudinal bore therethrough. The second expandable tubular member is delivered into the branch aperture so that the distal end of the second expandable tubular member is disposed within the second lumen and the proximal end of the second expandable tubular member is disposed within the branch aperture of the first tubular member and so that the longitudinal bore of the second expandable tubular member is in fluid communication with the longitudinal bore of the first longitudinal tubular member. The second expandable tubular member is then expanded in an amount sufficient to secure the second expandable tubular member within the second lumen and within the branch aperture of the first expandable tubular member.

[0013] Still another especially preferred method of making a bifurcated stent comprises the steps of delivering a first guide wire into the first lumen of a bifurcated vessel having a first lumen and a second lumen and delivering a second guide wire into the second lumen of the bifurcated vessel. A first expandable tubular member is prepared having a proximal end and a distal end and a longitudinal bore therethrough. The first expandable tubular member is provided with a branch aperture disposed between the proximal end and the distal end. The branch aperture communicates with the longitudinal bore and the branch aperture is sized and adapted to receive and secure a second expandable tubular member. The first expandable tubular member is mounted on a first balloon catheter and the first balloon catheter is mounted on the first guide wire. The first expandable tubular member is delivered to the first lumen of the bifurcated vessel so that the first expandable tubular member is disposed within the first lumen and the branch aperture communicates with the second lumen. A second balloon catheter is mounted on the second guide wire and the balloon portion of the second balloon catheter is delivered into the side-branch aperture. The second balloon catheter is inflated to widen the branch aperture in an amount sufficient to form a branch securing lip and to further align the branch aperture with the second lumen. The first balloon catheter is then inflated to expand the first expandable member in an amount sufficient to secure the first expandable member in the first lumen. The first and second balloon catheters are deflated and the second balloon catheter is removed. A second expandable tubular member is prepared having a proximal end and a distal end having longitudinal bore therethrough. The second expandable tubular member is mounted on the second balloon catheter. The second expandable tubular member, mounted on the second balloon catheter, is delivered into the branch aperture so that the distal end of the second expandable tubular member is disposed within the second lumen and the proximal end of the second expandable tubular member is disposed within the branch aperture of the first tubular member and so that the longitudinal bore of the second expandable tubular member is in fluid communication with the longitudinal bore of the first longitudinal member. The first balloon catheter is inflated. The second balloon catheter is inflated to expand the second expandable tubular member in an amount sufficient to secure the second expandable tubular member within the second lumen and within the branch aperture. As specific applications dictate, the portion of the first tubular stent defining the side branch aperture may be adapted to form a branch securing lip when the branch aperture is expanded a sufficient amount. In one embodiment, the first balloon catheter is inflated before the second balloon catheter is inflated and the first balloon catheter is left inflated until the second expandable tubular member is secured within the branch aperture by the second balloon catheter. In another embodiment, the first balloon catheter and the second balloon catheter are inflated simultaneously.

Claims

1. A method of making a stent comprising the steps of preparing a sheet (530) with a plurality of at least six sides (531, 532, 533, 534, 535, 536, 537, 538), rolling the sheet (530) into a tube and connecting two pairs of opposed sides (532, 538; 534, 536) of said sheet (530) to form a first tubular member (539) having a side branch aperture (529) communicating with the longitudinal bore (528) of said tube and

sized and adapted to receive a second tubular member (413),
characterized by the steps of:

preparing a "T" shaped sheet (530) having a first side (531), a second side (532), a third side (533), a fourth side (534), a fifth side (535), a sixth side (536), a seventh side (537) and an eighth side (538), and
connecting the second side (532) to the eighth side (538) and connecting the fourth side (534) to the sixth side (536), whereby the third side (533) and the seventh side (537) define said branch aperture (529) of said first tubular member (539) disposed between the first side (531) and the fifth side (535).

2. The method of claim 1, further **characterized by** the step of disposing and securing a second tubular member (512) having a longitudinal bore (513) within said branch aperture (529) of said first tubular member (539).

Patentansprüche

1. Verfahren zur Herstellung eines Stents, welches folgende Schritte aufweist:

Vorbereiten einer Bahn (530) mit einer Vielzahl von mindestens sechs Seiten (531, 532, 533, 534, 535, 536, 537, 538),
Rollen der Bahn (530) in eine Röhre und Verbinden von zwei Paaren von gegenüberliegenden Seiten (532, 538; 534, 536) der Bahn (530), um ein ersten röhrenförmiges Element (539) mit einer Seitenzweigöffnung (529) zu bilden, die mit der Längsbohrung (528) der Röhre in Verbindung steht und so bemessen und angepasst ist, um ein zweites röhrenförmiges Element (513) aufzunehmen,

gekennzeichnet durch folgende Schritte:

Vorbereitung einer "T"-förmigen Bahn (530) mit einer ersten Seite (531), einer zweiten Seite (532), einer dritten Seite (533), einer vierten Seite (534), einer fünften Seite (535), einer sechsten Seite (536), einer sieben Seite (537) und einer achten Seite (538), und
Verbinden der zweiten Seite (532) mit der achten Seite (538) und Verbinden der vierten Seite (534) mit der sechsten Seite (536), wobei die dritte Seite (533) und die siebte Seite (537) die Zweigöffnung (529) des ersten röhrenförmigen Elementes (539) bestimmen, welche zwischen der ersten Seite (531) und der fünften Seite (535) angeordnet ist.

2. Verfahren nach Anspruch 1, **gekennzeichnet durch** Vorsehen und Befestigen eines zweiten röhrenförmigen Elementes (512) mit einer Längsbohrung (513) innerhalb der Zweigöffnung (529) des ersten röhrenförmigen Elementes (539).

Revendications

1. Procédé pour fabriquer un stent comprenant les étapes consistant à:

préparer une feuille (530) comportant au moins six côtés (531, 532, 533, 534, 535, 536, 537, 538),
enrouler la feuille (530) sous la forme d'un tube et raccorder deux paires de côtés opposés (532, 538; 534, 536) de ladite feuille (530) pour former un premier élément tubulaire (539) comportant une ouverture de dérivation latérale (529) communiquant avec le perçage longitudinal (528) dudit tube et dimensionnée et adaptée pour recevoir un second élément tubulaire (413),

caractérisé par les étapes consistant à:

préparer une feuille en forme de "T" (530) possédant un premier côté (531), un second côté (532), un troisième côté (533), un quatrième côté (534), un cinquième côté (535), un sixième côté (536), un septième côté (537) et un huitième côté (538), et
raccorder le second côté (532) au huitième côté (538) et raccorder le quatrième côté (534) au sixième côté (536) de telle sorte que le troisième côté (533) et le septième côté (537) définissent ladite ouverture de dérivation (529) dudit premier élément tubulaire (539) disposé entre le premier côté (531) et le cinquième côté (535).

2. Procédé selon la revendication 1, **caractérisé en outre par** l'étape consistant à mettre en place et fixer un second élément tubulaire (512) comportant un perçage longitudinal (513) dans ladite ouverture de dérivation (529) dudit premier élément tubulaire (539).

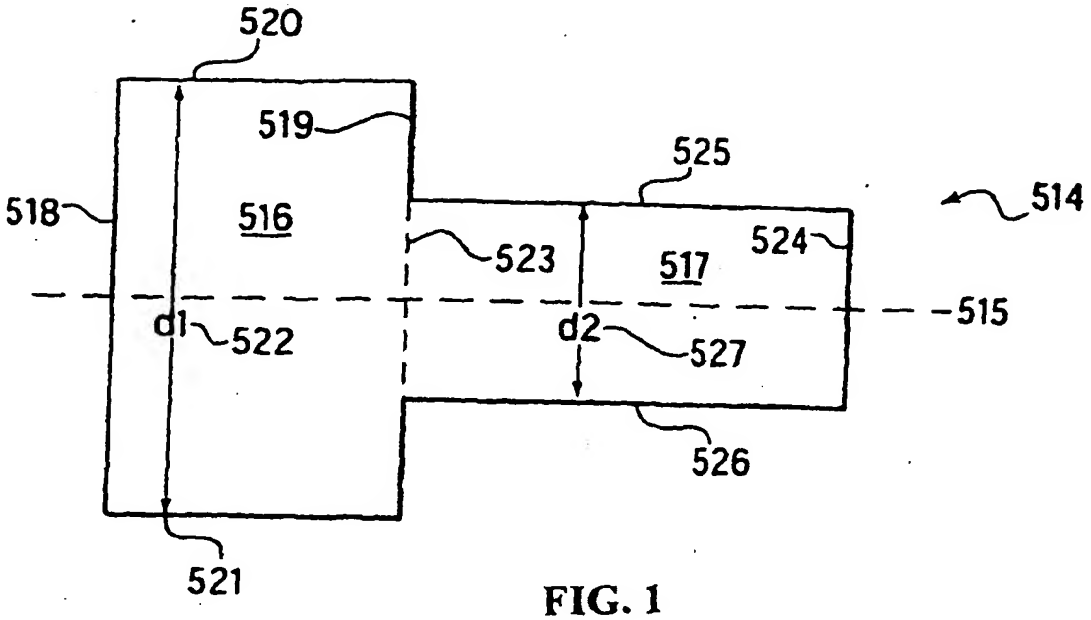

FIG. 1

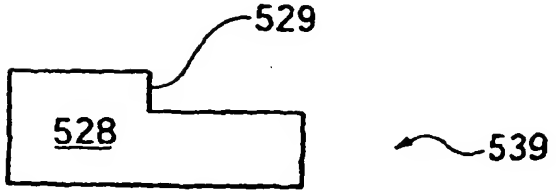

FIG. 1A

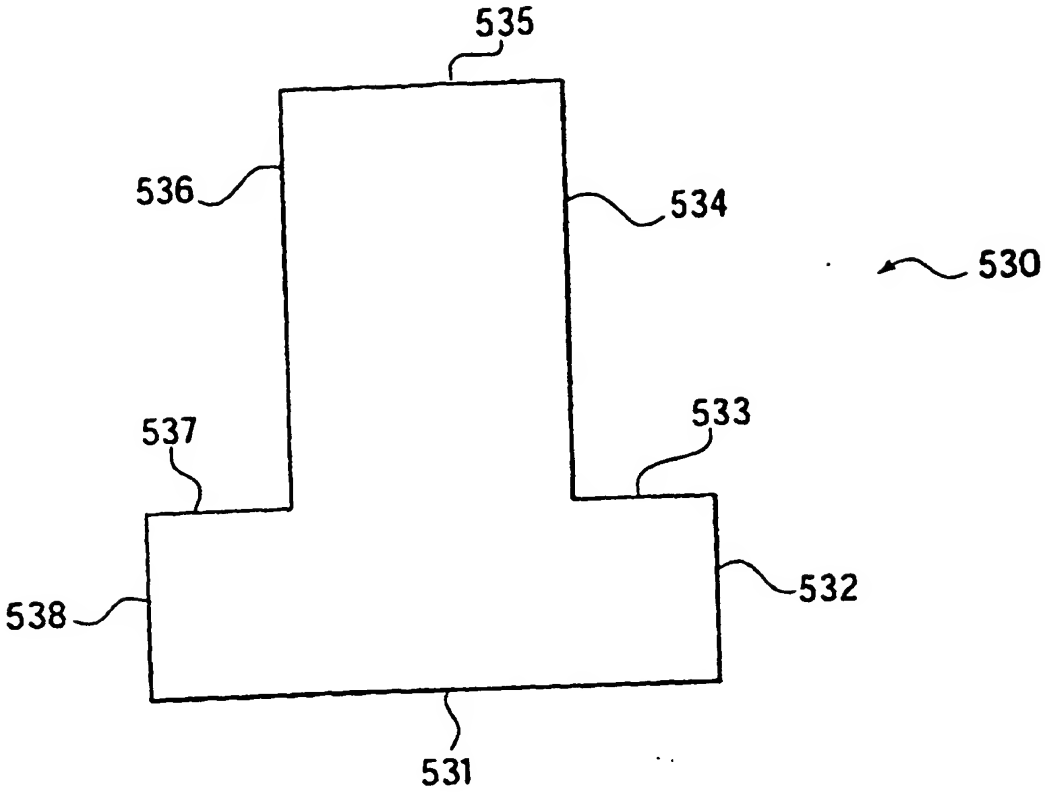

FIG. 2

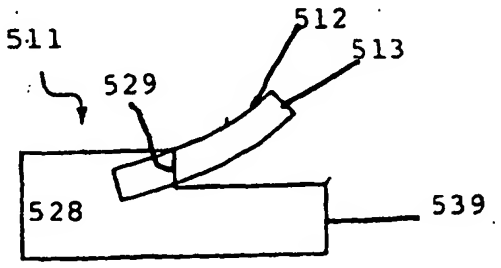

FIG. 3